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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,818	01/26/2004	Patricia A. Brown	AVSI-0033 (108328.00170)	8276
7590	01/11/2006		EXAMINER	
			SCHNIZER, RICHARD A	
			ART UNIT	PAPER NUMBER
			1635	
DATE MAILED: 01/11/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/764,818	BROWN ET AL.	
	Examiner	Art Unit	
	Richard Schnizer, Ph. D	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 October 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-9, 11-20, 22-28, 30-77, 79, 80, 86, 88, 89, 97 and 99 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-9, 11-20, 22-28, 30-77, 79, 80, 86, 88, 89, 97, and 99 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date, _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

An amendment was received and entered on 10/27/05. Applicant's election without traverse of Group 1 claims 1-9, 1-20, 22-28, and 30-76 is acknowledged.

After further consideration the previous restriction requirement is withdrawn in favor of the following requirement. This restriction requirement is identical to the previous requirement except that a further election of a nucleic acid sequence is required, as explained in more detail below.

Claims 1-9, 11-20, 22-28, 30-77, 79, 80, 86, 88, 89, 97, and 99 remain pending and are under consideration in this Office Action.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:
Groups 1-57. Claims 11-14, 20, 30-33, 39, 48-51, and 57-76 are drawn to methods of decreasing involuntary cull in farm animals, improving body condition score (BCS) in farm animals, or increasing milk production in dairy cows by delivering into muscle of the animal, or into tissue of the cow, an expression construct encoding a growth hormone releasing hormone (GHRH), classified in class 514, subclass 44. Note that each invention, 1-57, corresponds to a patentably distinct nucleic acids as discussed more fully below.

Groups 58-105. Claims 86 and 97 are drawn to methods of decreasing involuntary cull in farm animals, improving body condition score (BCS) in

farm animals by delivering to the farm animal an isolated growth hormone secretagogue molecule that facilitates growth hormone secretion in the farm animal, classified in class 530, subclass 324. Note that each invention, 1-57, corresponds to a patentably distinct nucleic acids as discussed more fully below.

The claims of groups 1-57 are drawn to a variety of patentably distinct nucleic acids, i.e. SEQ ID NOS: 11-14, 17-21, and nucleic acids encoding 48 variations of SEQ NO:6, including SEQ ID NOS: 1-5. The claims of groups 58-105 are drawn to 48 patentably distinct peptides set forth in SEQ ID NO:6. Applicant is required to elect a single nucleic acid or peptide for examination. This is not a species election requirement, but is a group restriction.

Claims 1-9, 15-19, 22-28, 34-38, 40-47, and 52-56 link(s) inventions 1-57. Claims 77, 79, 80, 88, 89, and 99 link inventions 58-105. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction

requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Groups 1-57 are related to groups 58-104 because each method could ultimately result in the delivery to tissues in an animal of GHRH. The methods are distinct because they require materially different substances with different functions. Groups 1 requires nucleic acids that encode variants of GHRH. These molecules must be delivered to appropriate cells that must express and secrete GHRH. As such the GHRH must be expressed in secretable form, i.e. with a signal sequence. Group 2 requires a mature peptide hormone that is delivered directly to cells in an animal, and is not secreted. Because the methods require physically and functionally distinct molecules, and have different modes of action, they are patentably distinct.

The nucleic acids required by inventions 1-57 are distinct inventions. It is not clear from the specification as filed that SEQ ID NOS: 11-14 and 17-21 have anything in common other than that they are expression vectors that may, or may not, encode a GHRH. The 48 possible variants of SEQ ID NO:6 encode distinct variants of GHRH which may have different functions in view of their different structures. As such these inventions are patentably distinct and properly restricted. Similarly the 48 different peptides encompassed by SEQ ID NO:6 are patentably distinct and properly restricted.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and their

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recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1 .143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1 .48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1 .48(b) and by the fee required under 37 CFR 1 .1741).

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Andrew Wang, can be reached at (571) 272-0811. The official central fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system

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provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Richard Schnizer, Ph.D.
Primary Examiner
Art Unit 1635